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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,693	02/15/2005	Camille Georges Wermuth	WERM 3001	8393

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BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

MAIL DATE	DELIVERY MODE
06/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,693	WERMUTH, CAMILLE GEORGES	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-5, 25-33* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Feb. 21, 2008 have been entered and considered carefully.

Claims 6, 12-24 have been canceled. Claims 1-5, 7-11, 25-33 are pending.

2. The rejection of claims 1, 7, 9, 12-13, 25, 31 under 35 USC 112 first paragraph is maintained for reason of record.

Applicants argued that applicants have deleted the term "solvate" but there is no reason to conclude that one skilled in the art would have difficulty in manufacturing or using the hydrates of the claims. Please note that, as it was clearly delineated by the skilled artisan in the field that "solvate" formation is highly unpredictable. Hydrate is a *limited* solvate wherein the solvent is water. Just because the claims are drawn to salt which is polar does not provide any support that all polar molecules can form hydrates. Please note that hydrates are specific chemical identities which are different from the non-hydrated form. Attorney provided no scientific basis for the statement the "Applicants submit that the claimed pamoate salts are polar compositions which can be expected to be solvated , to at least some degree, by a polar solvent such as water" (see p.8 of response). It is very confusing as to what attorney is referring to "some degree hydration". Two definition of hydrate by Evans or Brittain are hereby provided. "Hydrate" by definition is a "molecular adduct" which has molecules of water as part of its molecular formula (see last three lines of Brittain p.202, or Evans, molecular formulas on p.286); thus it is not a wet sample. Such compound, as clearly delineated by Braga et al. of record, can only be obtained after one *obtains* it. No prediction can be made. A survey of the specification, it is noted that none of the compounds forms hydrates.

3. The rejection of claims 7-8, 12, 25 under 35 USC 112 second paragraph is dropped in view of the cancellation and amendments to the claims.

4. The objection of claims 12-13 under 37 CFR 1.75 is dropped in view of the cancellation of the claims.

5. The rejections of claims 25-30 under 35 USC 112 first paragraph for lacking sufficient description and/or enablement are maintained for reason of record.

The gist of applicants' argument is that the salt has 5HT activity therefore can prophylaxis and treat all stress-related affective disorder, and PTO has allowed it in SN 10/486,935.

The very detailed and explicit delineation with state-of-the-art searches for the term "stress-related affective disorder" has been provided in the previous office action and hereby incorporated by reference. Applicants provided no factual evidence that what is the scope of the term being defined by the art. Further, the SN 10/486,925 is now US 7,189,742. Please note that the method of treatment claims 13-21 are drawn to treat depression, anxiety or sleep apnea same as delineated in the previous office action.

6. The rejection of claims 7-11, 25-33 under 35 USC 112 first paragraph for lacking sufficient enablement is maintained for reason of record.

Applicants argued that because the prior art and the instant application recited that the compounds reduce 5HT turnover therefore the specification has listed many disorder potentially treatable by the compound. This is not persuasive, while mechanism can indicate some understanding how a drug works, the enablement requirement must be based upon known efficacy, route of administration and dosage of a given drug. As it was explained in the previous office action, the prior art does not support the diversity of disorders of claim 26 or the unspecific scope of claim 25 or formulating a dosage composition containing such salts.

7. The rejection of claims 1-2, 4-9, 11, 25-31, 33 under 35 USC 103(a) over Gittos et al. '151 or '771 supplemented with RN 103353-87-3 in view of Berge et al is maintained for reason of record.

Applicants presented contradictory arguments. On one had, applicants argued that other than AGN 2979, the other compounds of claim 1 have not been tested but expected to have similar toxicity because there are only small genus of compounds (p.11 response). On the other hand, applicants presented that there is "…magnitude of the problem faced by one skilled in the art" that which salt is effective, toxic or less toxic etc. (p.12 response). There is no factual basis

for the attorney to present such contradictory conclusion. Drug toxicity is a compound by compound case. Absent of factual evidence, no conclusion/extrapolation can be drawn to the other compounds whether the hydrochloride salt of them are toxic or not toxic. By the same token, in absence of factual evidence, there is no conclusion can be drawn to whether pamoate of the other compounds of claim 1 will be toxic or less toxic from its hydrochloride salt. One example can be seen in case of cycloguanil, for which the hydrochloride salt is nontoxic (Holfels et al.) while the pamoate is toxic (Kaump et al.).

In establishing a prima facie case of obviousness, the teaching, suggestion and motivation from the prior art which provide reasonable expectation of success is the standard. The mere fact that hydrochloride salt of AGN 2979 was chosen is based on common FDA approval would be given to such salt. The mere fact that it is until clinical trial that toxicity was discovered, provided evidence that no prediction should be given to toxicity without factual evidence. While FDA choice is the motivation for one skilled in the art to choose, thus, prima facie obvious, absolute prediction must come from factual evidence. The establishment of a prima facie case, however, does not required absolute predictability only reasonable expectation. See Ex parte Erlich 3USPQ2d 1011. The fact in the record does not provide any evidence that another compound would have toxic hydrochloride or pamoate would be a solution to that compound.

The high degree of unpredictability of which salt will cause efficacy which will cause toxicity is the reason that claim 3 AGN 2979 pamoate is allowable.

8. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun 5, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625